45. (Amended) The pharmaceutical or cosmetic composition of claim 37, wherein said carbon backbone of said fatty alcohol has at least one hydroxyl group at position α and β .

46. (Amended) The pharmaceutical or cosmetic composition claim 37, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at positions 8-14.

47. (Amended) The pharmaceutical or cosmetic composition of claim 37, wherein said solidifying agent includes a 12-hydroxy fatty acid.

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-103 are in this case. Claims 6, 13-25, 31, 42 and 52-103 were withdrawn from consideration under a restriction requirement as drawn to a non-elected invention/species. Claims 1-5, 7-12, 26-30, 32-41 and 43-51 have been rejected.

By this amendment, claims 2, 3, 27, 28, 38 and 39 have been canceled and claims 1, 7-11, 26, 37, 41 and 44-47 have been amended.

Attached herewith is a marked up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with marks to show changes made".

Election

Claims 6, 31, 42 and 52 were withdrawn from further consideration as being directed to a non-elected species. In view of the amendments made to claims 1, 26 and 37, from which claims 6, 31, 42 and 52 directly or indirectly depend, and further in view of the arguments set forth hereinbelow, it is Applicant's opinion that the generic claims 1, 26 and 37 are allowable, hence requesting the cancellation of the withdrawal of claims 6, 31, 42 and 52 from consideration.

35 USC § 103(a) Rejections - Vatter et al.; and Vatter et al. in view of Geria

The Examiner has rejected claims 1-5, 7-12, 26-30, 32-41 and 43-50 under 35 USC § 103(a) as being unpatentable over Vatter et al. The Examiner has further rejected claim 51 under 35 USC § 103(a) as being unpatentable over Vatter et al. and further in view of Geria. The Examiner's rejections are respectfully traversed. Claims 2, 3, 27, 28, 38 and 39 have now been canceled, thereby rendering moot the Examiner's rejections with respect thereto. Claims 1, 7-11, 26, 37, 41 and 44-47 have now been amended.

In particular, claim 1 has now been amended to include the limitations of now canceled claims 2 and 3; claim 26 has now been amended to include the limitations of now canceled claims 27 and 28, whereas claim 37 has now been amended to include the limitations of now canceled claims 38 and 39.

Hence, each of the independent claims include the following limitations:

- 1. The solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbon atoms in its carbon backbone; and
- 2. The solidifying agent includes a substance selected such that under ambient conditions, the carrier, oil or composition is semi-solid at rest and liquefies upon application of shear forces thereto.

The later property enables application of a mixture as a semi-solid state to a body surface, which subsequently becomes substantially liquid and therefore more spreadable and penetrable when rubbed onto the body surface. Thus, one of the most important properties of the carrier and compositions of the present invention is that they are semi-solid at rest and that they liquefy upon application of shear forces thereto. Semi-solid hydrophobic formulations are important not only for the pharmaceutical market but also for cosmetic products, such as carriers of sunscreen compounds, oil-soluble plant extracts, materials for scrubbing purposes and other active and non-active cosmetic

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ingredients. Unlike aqueous liquids, which are rather easy to solidify due to their hydrogen bond forming ability, oils are difficult to solidify. Several methods have been proposed to increase the viscosity of oils. Various gelling agent, such as inorganic complexing agents, polymers and copolymers, and polysaccharides have been previously described in the context of solidifying oils for use in food and cosmetics. The use of waxes, fatty alcohols, fatty acids and 12 hydroxy stearic acid in solidifying waste oils, in order to facilitate the removal of such oils have also been described. Pharmaceutical compositions, comprising an oil and beeswax as a gelling agent, which form a netted framework of the beeswax and form a film after application on a body surface are also known.

The prior art described above and the prior art references cited by the Examiner fail to teach a carrier or composition for topical application which includes at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and/or at least one fatty acid, having at least 18 carbon atoms in its carbon backbone, which is semi-solid at rest and which liquefies upon application of shear forces thereto.

It is, thus, the Applicant's opinion that amended independent claims 1, 26 and 37 are not rendered obvious in view of Vatter et al.

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Hence, it is the Applicant's opinion that amended independent claims 1, 26

and 37 are allowable, rendering claims which directly or indirectly claims

depending therefrom, also allowable.

In view of the above amendments and remarks it is respectfully submitted

that claims 1, 4-6, 7-12, 26, 29-31, 32-37, 40-42 and 43-52 are now in condition

for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

Sol Sheinbein

Attorney for Applicant Registration No. 25,457

Date: 17 December 2001.

Encl.:

Three months extension fees;

VERSION WITH MARKINGS TO SHOW CHANGES MADE; and



VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 2, 3, 27, 28, 38 and 39 have now been canceled.

Claims 1, 7-12, 26, 37, 41 and 44-47 have now been amended as follows:

- 1. (Amended) A pharmaceutical or cosmetic carrier comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbon atoms in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.
- 7. (Amended) The pharmaceutical or cosmetic carrier of claim $2\underline{1}$, wherein said solidifying agent has at least one alkyl group side chain in its carbon backbone.
- 8. (Amended) The pharmaceutical or cosmetic carrier or composition of claim $2\underline{1}$, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at position α and β .

- 9. (Amended) The pharmaceutical or cosmetic carrier of claim $2\underline{1}$, wherein said carbon backbone of said fatty alcohol has at least one hydroxyl group at position α and β .
- 10. (Amended) The pharmaceutical or cosmetic carrier of claim 21, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at positions 8-14.
- 11. (Amended) The pharmaceutical or cosmetic carrier of claim $2\underline{1}$, wherein said solidifying agent includes a 12-hydroxy fatty acid.
- 26. (Amended) A pharmaceutical or cosmetic composition comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein at least one of said solidifying agent and said hydrophobic solvent has a therapeutic or cosmetic beneficial effect, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbon atoms in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

- 37. (Amended) A pharmaceutical or cosmetic composition comprising:
- (a) a pharmaceutical or cosmetic carrier containing, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent; and
- (b) a therapeutically or cosmetically effective amount of a biologically active substance-:

wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbon atoms in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

41. (Amended) The pharmaceutical or cosmetic composition of claim 3837, wherein said hydrophobic solvent includes an oil selected from the group consisting of olive oil, soybean oil, canola oil, rapeseed oil, cottonseed oil, coconut oil, palm oil, sesame oil, sunflower oil, safflower oil, rice bran oil, borage seed oil, syzigium aromaticum oil, hempseed oil, herring oil, cod-liver oil, salmon oil, corn oil, flaxseed oil, wheat germ oil, rape seed oil, evening primrose oil, rosehip oil, tea tree oil, melaleuca oil and jojova oil.

- 44. (Amended) The pharmaceutical or cosmetic composition of claim 3837, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at position α and β .
- 45. (Amended) The pharmaceutical or cosmetic composition of claim $\frac{3837}{1}$, wherein said carbon backbone of said fatty alcohol has at least one hydroxyl group at position α and β .
- 46. (Amended) The pharmaceutical or cosmetic composition claim 3837, wherein said carbon backbone of said fatty acid or said fatty alcohol has at least one hydroxyl group at positions 8-14.
- 47. (Amended) The pharmaceutical or cosmetic composition of claim 3837, wherein said solidifying agent includes a 12-hydroxy fatty acid.